PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE	Application Number		10567594	
	Filing Date		2006-12-12	
	First Named Inventor Elisab		sabeth Arkenau-Maric	
(Not for submission under 37 CFR 1.99)	Art Unit		1615	
	Examiner Name	Hase	n Syed Ahmed	
	Attorney Docket Number		107101-47	

	U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	tent Number Kind Code¹		Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear			
	1	4690822	А	1987-09-01	UEMURA ET AL.				
	2	5051261	А	1991-09-24	MCGINITY ET AL.				
	3	6348469	B1	2002-02-19	SETH				
	4	6375963	B1	2002-04-23	REPKA ET AL.				
	5	6399100	B1	2002-06-04	CLANCY ET AL.				
	6	6562375	B1	2003-05-13	SAKO ET AL.				
	7	6753009	B2	2004-06-22	LUBER ET AL.				
	8	5620697	А	1997-04-15	TORMALA ET AL.	corresponds to JP 8 505076			

(Not for submission under 37 CFR 1.99)

Application Number		10567594	
Filing Date		2006-12-12	
First Named Inventor	Elisat	oeth Arkenau-Maric	
Art Unit		1615	
Examiner Name Hase		n Syed Ahmed	
Attorney Docket Numb	er	107101-47	

9	6000390	B1	2001-09-18	GRABOWSKI ET AL.	
10	5741519	А	1998-04-21	ROSENBERG ET AL.	
11	5939099	А	1999-08-17	GRABOWSKI ET AL.	
12	6120802	А	2000-09-19	BREITENBACH ET AL.	
13	6001391	А	1999-12-14	ZEIDLER ET AL.	
14	6318650	B1	2001-11-20	BREITENBACH ET AL.	
15	4880585	А	1989-11-14	KLIMESCH ET AL.	
16	4957668	А	1990-09-18	PLACKARD ET AL.	
17	5562920	А	199 9-12- 14	DEMMER ET AL.	
18	6821588	B1	2004-11-23	HAMMER ET AL.	

U.S.PATENT APPLICATION PUBLICATIONS

Application Number		10567594		
Filing Date		2006-12-12		
First Named Inventor	Elisat	lisabeth Arkenau-Maric		
Art Unit		1615		
Examiner Name	Hase	n Syed Ahmed		
Attorney Docket Number		107101-47		

Examiner Initial*			Publication Number	Kind Publication Code ¹ Date		ation	Name of Patentee or Applicant of cited Document			Pages,Columns,Lines where Relevant Passages or Relev Figures Appear	
	1		20040052844	A1	2004-0	3-18	HSIAO ET AL				
	2	_	20050095291	A1	2005-0	5-05	BENJAMIN O	SHLACK ET AL.			
	3		20030125347	A1	2003-0	7-03	ANDERSON I	≣T AL.			
	4		20070269505	69505 A1	2007-1	1-22	FLATH ET AL.				
	5		20020132359	A1 2002-09-19		WATERMAN					
If you wis	h to ad	ld a	dditional U.S. Pub	lished Ap	-		n information	please click the Add	d butto	on.	
Examiner Initial*	Cite No		reign Document mber ³	Country Code ² i	y	Kind Code4	Publication	Name of Patented Applicant of cited Document		Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1	054	14144	EP		A1	1993-06-02	BASF AG		English abstract enclosed	
	2	063	86370	EP		A1	1995-02-01	EURO CELTIQUE	SA		
	3	064	17448	EP		A1	1995-04-12	EURO CELTIQUE	SA		

Application Number		10567594	
Filing Date		2006-12-12	
First Named Inventor	Elisat	peth Arkenau-Maric	
Art Unit		1615	
Examiner Name	Hase	n Syed Ahmed	
Attorney Docket Numb	er	107101-47	

3	0675710	EP	A1	1995-10-11	SAITEC SRL	corresponds to US 5662935 A	
5	0756480	EP	A1	1997-02-05	BASF AG	corresponds to US 6290990 B1	
6	0760654	EP	A1	1997-03-12	BASF AG	corresponds to US 5741519 A	
7	0785775	EP	A1	1997-07-30	EURO CELTIQUE SA	corresponds to US 5958452 A	
8	0809488	EP	A1	1997-12-03	BASF AG	corresponds to US 5,939,099	
9	0857062	EP	A2	1998-08-12	BASF AG	corresponds to US 6,120,802	
10	0864324	EP	A1	1998-09-16	BASF AG	corresponds to US 6,001,391	
11	0864326	EP	A2	1998-09-16	KNOLL AG	English abstract attached	
12	0988106	EP	A1	2000-03-29	BASF AG	corresponds to US 6,318,650	
13	1014941	EP	A1	2000-07-05	UNIV TEXAS		
14	1293196	EP	A2	2003-03-19	PHARMA PASS II LLC		

Application Number		10567594
Filing Date		2006-12-12
First Named Inventor Elisab		oeth Arkenau-Maric
Art Unit		1615
Examiner Name Hase		n Syed Ahmed
Attorney Docket Number		107101-47

19	1527775	EP	A1	2005-04-05	EURO CELTIQUE SA	
16	02/088217	WO	A1	2002-11-07	UNION CARBIDE CHEMICALS & PLASTICS TECHNOLOGY CORP	
17	03/026624	WO	A1	2003-04-03	MCNEIL-PPC, INC	
18	03/028990	WO	A1	2003-04-10	MCNEIL-PPC, INC	
19	03/035177	WO	A2	2003-05-01	DEPOMED, INC.	
20	03/092648	wo	A1	2003-11-13	ALZA CORPORATION	
21	04/066910	WO	A2	2004-08-12	GLENMARK PHARMACEUTICALS LTD.	
22	04/084869	WO	A1	2004-10-07	EGALET AS	
23	04/093801	WO	A2	2004-11-04	EURO-CELTIQUE S.A	
24	04/100894	WO	A2	2004-11-25	SHIRE LABORATORIES, INC.	
25	05/032524	WO	A2	2005-04-14	ALZA CORPORATION	

Application Number		10567594	
Filing Date		2006-12-12	
First Named Inventor	Elisat	eth Arkenau-Maric	
Art Unit		1615	
Examiner Name Hase		n Syed Ahmed	
Attorney Docket Numb	er	107101-47	

26	05/065646	wo	A2	2005-04-14	ALZA CORPORATION		
	00/000010			2000 0 1 1 1	NEED CORN OR WHOM		
27	0240906	EP	A2	1987-10-14	BASF AG	corresponds to US 4880585 A	
28	2003026743	WO	A2	2003-04-03	Penwest Pharmaceuticals Company		
29	05/053587	wo	A1	2005-06-16	ACURA PHARMACEUTICALS INC		
30	05/055981	WO	A2	2005-06-23	EURO CELTIQUE SA		
31	90/003776	wo	A1	1990-04-19	ZETACHRON INC		
32	09/135680	WO	A1	2009-11-12	GRUENENTHAL GMBH		
33	09/092601	wo	A1	2009-07-30	GRUENENTHAL GMBH		
30	07/085024	wo	A2	2007-07-26	ABBOTT GMBH & CO		
35	07/005716	WO	A2	2007-01-11	CINERGEN LLC		
36	03-501737	JP	А	1991-04-18	ZETACHRON INC	corresponds to English- language equivalent WO 90/003776	

Application Number		10567594
Filing Date		2006-12-12
First Named Inventor Elisab		peth Arkenau-Maric
Art Unit		1615
Examiner Name	Hasen Syed Ahmed	
Attorney Docket Number		107101-47

			-	Y	-	*	
37	04/004693	wo	A1	2004-01-15	COLLGEGIUM PHARMACEUTICAL		
38	19800689	DE	C1	1999-07-15	DELORO STELLITE GMBH	abstract is attached	
39	8-505076	JP	А	1996-06-04	Tormala et al	Corresponds to US 5620697. A copy is provided.	
to a	I dd additional Fore	<u> </u>	ment citatio	l on information p	I please click the Add but	ton	<u> </u>
		NON-P	ATENT LIT	ERATURE DO	CUMENTS		
Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.					T5	
1	Maggi. Therapeutic Potential of Capsaicin-like Molecules. 1Life Sciences, Vol. 51, pp. 1777-1781, 1992.						
Handbuch der Kunststoff-Extrusionstechnik 1, "Grundlagen" in Chapter 1.2 "Klassifizierung von Extrudern", pgs 3 1989. 3 2.9 Methoden der pharmazeutischen Technologie 143-144, 1997.					von Extrudern", pgs 3-7.		
4	Dachille, F. et al., "High-Pressure Phase Transformation in Laboratory Mechanical Mixers and Mortars", 1960., Nature, 186, pp. 1-2 (abstract)						
Freed et al. pH control of nucleophilic/electrophilic oxidation. International Journal of Pharmaceutics. 2008, Vol 357, Pages 180-188.							
		Waterman et al. Stabilization of Pharmaceuticals to Oxidative Degradation. Pharmaceutical Development and Technology. 2002, Vol 7, No. 1, Pages 1-32.					
3		Handbuch der Ku 1989. 2.9 Methoden der Dachille, F. et al., 186, pp. 1-2 (abs	Handbuch der Kunststoff-Extrusions 1989. 2.9 Methoden der pharmazeutischer Dachille, F. et al., "High-Pressure Ph 186, pp. 1-2 (abstract) Freed et al. pH control of nucleophili	Handbuch der Kunststoff-Extrusionstechnik 1, "G 1989. 2.9 Methoden der pharmazeutischen Technologi Dachille, F. et al., "High-Pressure Phase Transfo 186, pp. 1-2 (abstract) Freed et al. pH control of nucleophilic/electrophili	Handbuch der Kunststoff-Extrusionstechnik 1, "Grundlagen" in Cl 1989. 2.9 Methoden der pharmazeutischen Technologie 143-144, 1997 Dachille, F. et al., "High-Pressure Phase Transformation in Labor 186, pp. 1-2 (abstract) Freed et al. pH control of nucleophilic/electrophilic oxidation. Inter	Handbuch der Kunststoff-Extrusionstechnik 1, "Grundlagen" in Chapter 1.2 "Klassifizierung 1989. 2.9 Methoden der pharmazeutischen Technologie 143-144, 1997. Dachille, F. et al., "High-Pressure Phase Transformation in Laboratory Mechanical Mixers a 186, pp. 1-2 (abstract) Freed et al. pH control of nucleophilic/electrophilic oxidation. International Journal of Pharm	2.9 Methoden der pharmazeutischen Technologie 143-144, 1997. Dachille, F. et al., "High-Pressure Phase Transformation in Laboratory Mechanical Mixers and Mortars", 1960., Nature, 186, pp. 1-2 (abstract) Freed et al. pH control of nucleophilic/electrophilic oxidation. International Journal of Pharmaceutics. 2008, Vol 357,

Application Number		10567594
Filing Date		2006-12-12
First Named Inventor Elisab		peth Arkenau-Maric
Art Unit		1615
Examiner Name	Hasen Syed Ahmed	
Attorney Docket Number		107101-47

	-	7						
	7	Maggi, L. et al., "High molecular weight polyethylene oxides (PEOs) as an alternative to HPMC in controlled release dosage form", 2000, International Journal of Pharmaceutics, 195 pp, 229-238						
	8	Conversion of 18.8 kiloponds to newtons, http://www.unitconversion.org/force/newtons-to-kiloponds-conversion.html on July 5, 2011						
	9	Waltimo et al. A novel bite force recorder and maximal isometric bite force values for healthy young adults. Scand J Dent Res. 1993, Vol 101, Pages 171-5.						
	10	Waltimo et al. Maximal bite force and its association with signs and symptoms of crandiomandibular disorders in young Finnish non-patients. Acta Odonol. Scand. 1995, Vol 53, Pages 254-258.						
If you wis	sh to a	dd add	litional non-patent literature document citation information please click	the Add	button			
			EXAMINER SIGNATURE					
Examine	r Sign	ature	Date Cons	idered				
citation if	Codes 5T.3). 3	of USPTO For Japa t by the a	reference considered, whether or not citation is in conformance with M rmance and not considered. Include copy of this form with next common O Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued to an ease patent documents, the indication of the year of the reign of the Emperor must precappropriate symbols as indicated on the document under WIPO Standard ST.16 if possible in is attached.	nication he docume ede the se	to applicant. ent, by the two-letter code (W rial number of the patent doc	ument.		

(Not for submission under 37 CFR 1.99)

Application Number		10567594	
Filing Date		2006-12-12	
First Named Inventor Elisab		eth Arkenau-Maric	
Art Unit		1615	
Examiner Name Hasen		n Syed Ahmed	
Attorney Docket Number		107101-47	

CERTIFICATION STATEMENT								
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):								
	That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).							
OR								
	That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).							
	See attached certification statement.							
\boxtimes	The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.							
	A certification statement is not submitted herewith.							
SIGNATURE A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.								
Sigr	nature	/Kurt G. Briscoe/	Date (YYYY-MM-DD)	2011-10-06				
Nan	ne/Print	Kurt G. Briscoe	Registration Number	33141				
		•	·					

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.